

IPERGAY, PrEP and the benefits of involving communities

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AIDES

Introduction

- What information should I share with you today?
 - *Scientific data or...*
 - Narrative - our experience
 - Advocacy strategy and future steps
- From what point of view?
 - Researcher
 - Activist
 - CBO representative

Our recent history with PrEP

- 2009: AIDES board of directors takes the decision to participate in Ipergay
- 2009: Preparatory Ipergay survey
- 2010: Community-based consultation TRT-5
- 2012- Today: ANRS-IPERGAY trial
- 2013: ANRS working group – RTU PrEP
- 2014: FlashPrEP survey
- 2014: IPERGAY: stop placebo arm
- **201?: Access to PrEP**



2010 - IAS Vienna



2012 - FDA Approval



2014 USA PHS/OMS Guidelines



2014 - PROUD results on efficacy

TRT-5 Community Consultation (1)

- **2010 – 300 participants – 10 French cities**
- **Opportunity for the HIV/AIDS associations**
 - to work together on this topic
 - to involve LGBT associations in rethinking prevention
- **PrEP trial project as an innovative field is perceived as an opportunity**
 - to inform on ongoing prevention research & new prevention tools
 - to mobilize or remobilize LGBT bodies and gay men on HIV prevention among gay men
- **Mobilization, discussions, debate on HIV prevention, strategies and tools**

Thanks to François Berdougou for this slide

TRT-5 Community Consultation (2)

- **Regarding the process**

- Lack of time to build and implement the process
- Lack of time during the meetings
- Not really a “community consultation” but an “associative consultation”

- **Regarding the content**

- Confusion between “PrEP as a tool” and “PrEP research”
- To inform and consult? or To mobilize and recruit?

Thanks to François Berdougo for this slide



ipergay

ANRS

Intervention Préventive
de l'Exposition aux Risques
avec et pour les Gays

Why we did it? Because...

- An opportunity to fulfill a **need** (survey 2009)
- A possibility to include and ensure counseling and **personal coaching** regarding sexual health
- Integration of a **psychosocial** approach in the biomedical project
- Social transformation
- Potential benefits of iPrEP
 - Higher adherence: more convenient dosing regimen
 - Better safety: lower drug exposure (kidneys, bones)
 - Cost-effectiveness

Study Design

Effectiveness of “on demand” PrEP Randomized placebo-controlled trial

- High risk MSM
- Condomless anal sex with ≥ 2 partners within 6 m
- eGFR > 60 mL/mn

Full prevention services*
TDF/FTC before and after sex
(n=950)

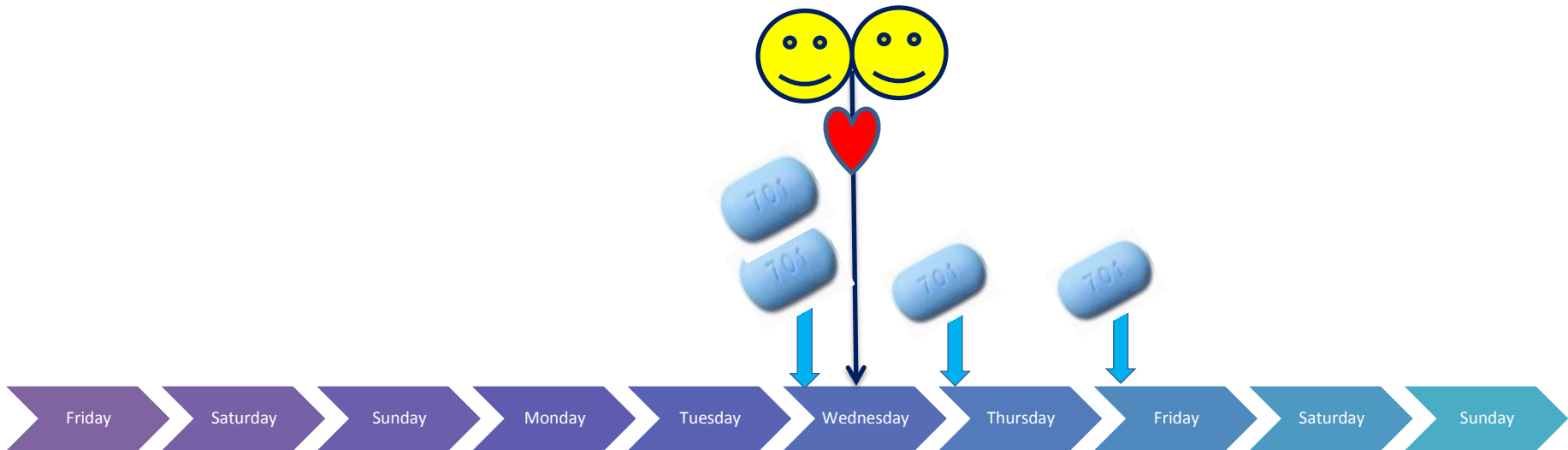
Full prevention services*
placebo before and after sex
(n=950)

- Counseling, testing for STI, condoms, vaccination, PEP, self-support groups
- Primary endpoint : HIV infection
- Incidence of HIV-infection: **3%PY**, 50% efficacy, 64 events

Thanks to Prof. Jean-Michel Molina for this slide

Ipergay : Event-Driven iPrEP

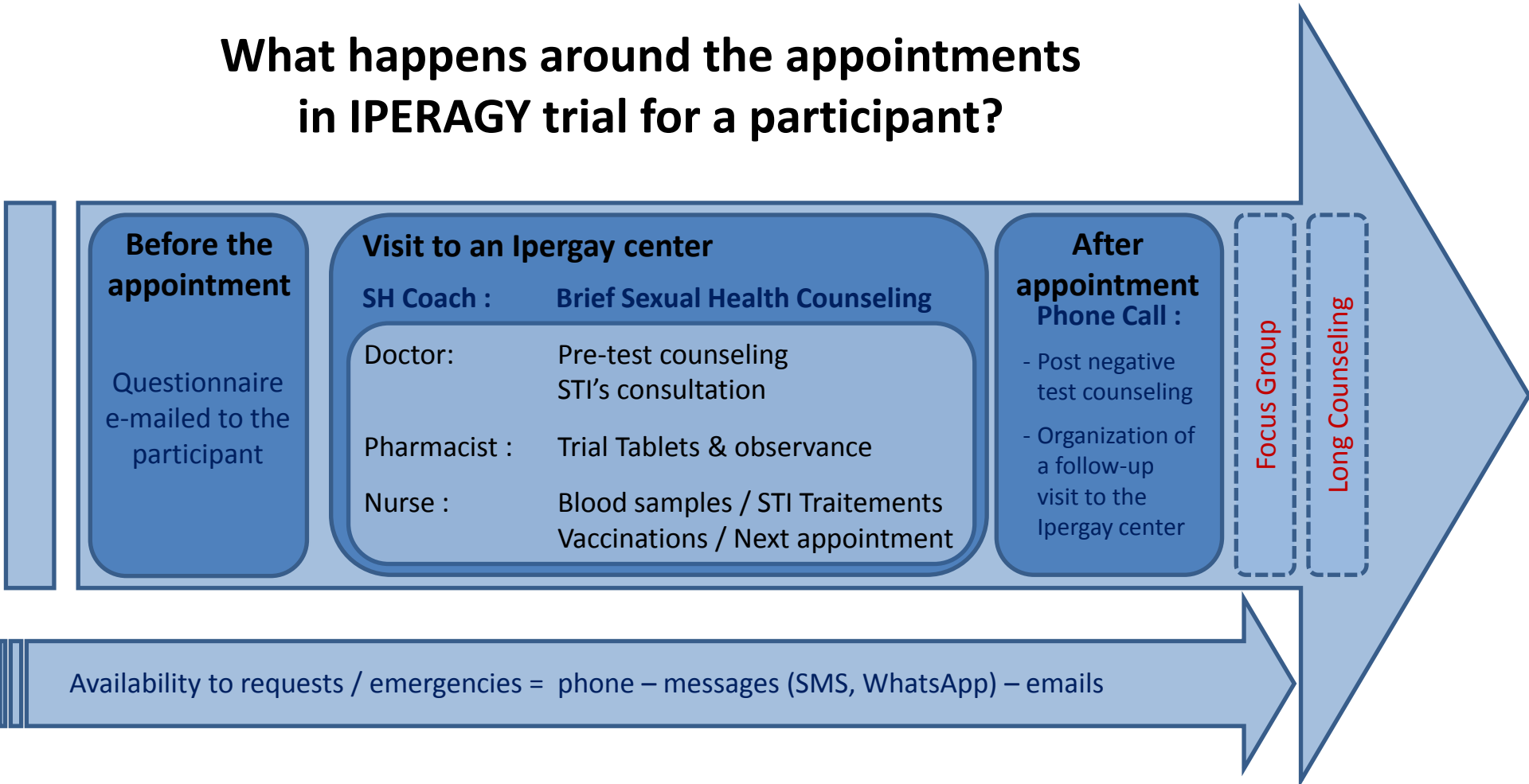
- ✓ 2 tablets (Truvada® / placebo) 2-24 hours before sex
- ✓ 1 tablet (Truvada® / placebo) 24 hours later
- ✓ 1 tablet (Truvada® / placebo) 48 hours later
- ✓ Retention rate = around 85 %



Thanks to Prof. Jean-Michel Molina for this slide

Ipergay : Event-Driven iPrEP

What happens around the appointments in IPERAGY trial for a participant?



Thanks to Stéphane Morel for this slide

Press release

A SIGNIFICANT BREAKTHROUGH IN THE FIGHT
AGAINST HIV/AIDS

A drug taken at the time of sexual intercourse
effectively reduces the risk of infection

=====
The ANRS IPERGAY trial demonstrates the effectiveness of a preventive treatment (antiretroviral treatment) against HIV/AIDS when taken at the time of sexual intercourse. All trial participants will now benefit from this prophylaxis.
=====

- PROUD breaking news
- Independent board: results of Ipergay
- **IPEGAY breaking news 29/10/2014**
- What impact of stopping the placebo arm?
- What about peers (sexual health coach)? Pride, recognition, emotion. “We are making history”
- Current reflection regarding the following essay steps’



Enquête Flash PrEP



Objectifs



To characterize HIV- people awareness regarding PrEP, willingness and intention to use PrEP

What populations are informed? What populations are willing to take PrEP? And what proportion among them declare to have the intention to get PrEP?

What are the reasons for being interested/or having the intention and vice versa?

To characterize informal PrEP use

Preliminary Results



- 3024 respondents
- Internet and paper survey
- 33.6% aware of PrEP before answering the questionnaire
- Intention to use PrEP is available : migrants, heterosexual men, most-at-risk populations, informal PrEP users
- 4.5 % informal use of PrEP (75% MSM, 12.6% heterosexual men and 9.4% women)
- Much more to come....

Next Steps

- **Advocacy national strategy:**
 - Open-label inside Ipergay
 - Open-label PrEP in France
 - Ask to medical associations to establish guidelines/recommendations concerning informal PrEP use
 - Brig value to the coach/support provided by peers
- **Advocacy European strategy:**
 - ECDC
 - EATG
 - Others
- **Dissemination of Flash-PrEP survey results:** health-policy makers, people participating in the survey, associative and scientific arena

Muchas gracias...

drojas@aides.org

www.aides.org

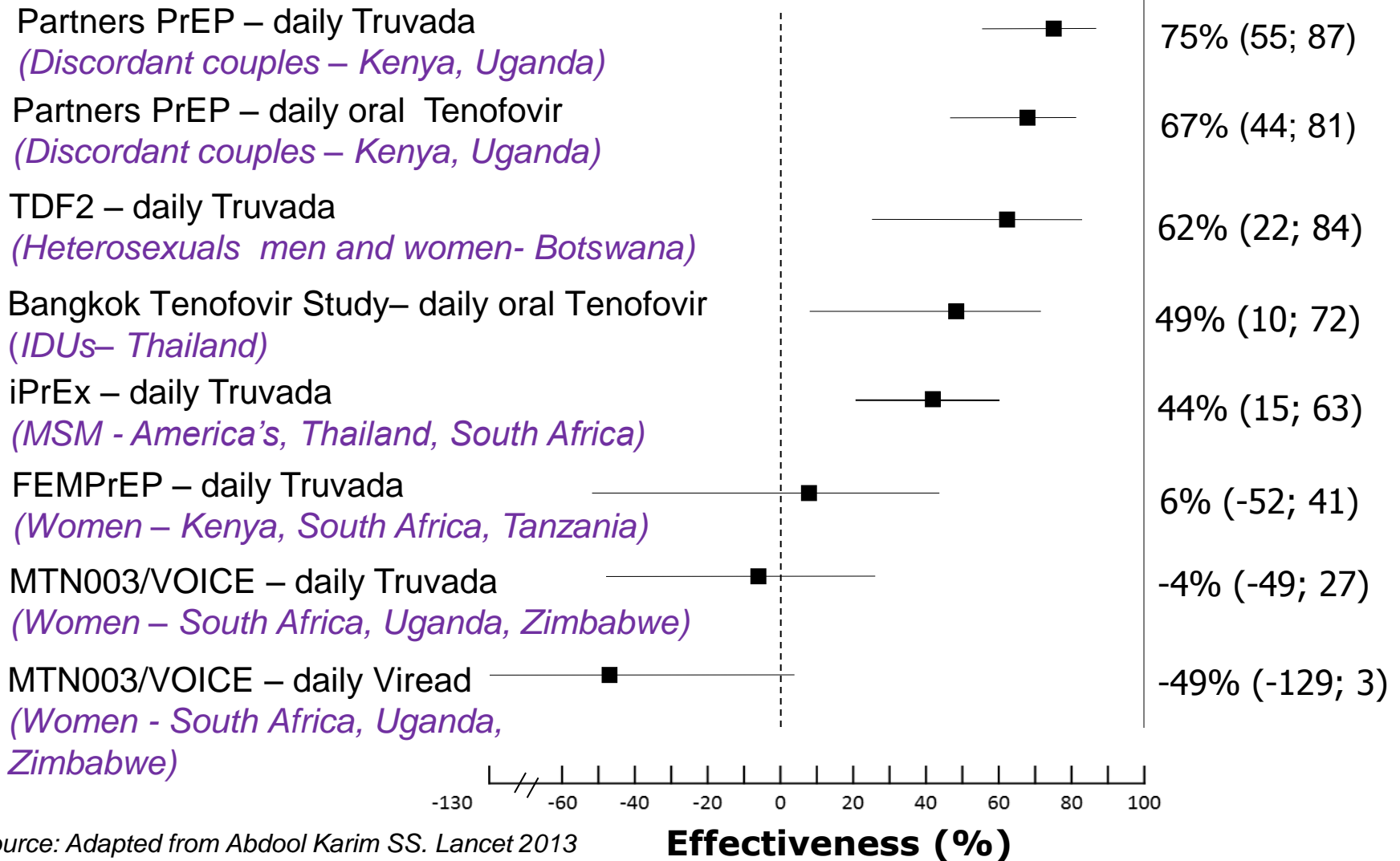
www.ipergay.fr

UK PROUD pilot study update

Mitzy Gafos on behalf of the PROUD study

Clinical trial evidence for oral PrEP

Effect size (CI)



Source: Adapted from Abdool Karim SS. Lancet 2013

UK Position

- **March 2011:** BHIVA-BASHH position statement
 - Need evidence for the value of PrEP in the UK
 - Recommend that ad hoc prescribing of PrEP be avoided and PrEP be prescribed in the context of a clinical research study in order to collect UK specific information as quickly as possible.

International Journal of STD & AIDS 2012; 23: 1-4

PROUD Pilot Study

PRe-exposure **O**ption for reducing
HIV in the **UK**: an open-label
randomisation to immediate or
Deferred daily Truvada for **HIV**
negative gay men

PROUD Pilot

500 MSM reporting UAI last/next 90days
18+, Willing to take a pill

Randomize HIV negative MSM
(exclude if on treatment for hepB/Truvada contra-indicated)

Truvada **NOW** and MI+

Truvada **IN 12M** and MI+

Follow **3 monthly** for up to 24 months

Follow up
extended to
end of study

Main endpoints: recruitment and retention

Effectiveness

Methods

- Study recruitment: Nov 2012-Apr 2014
- Study clinics: 13 sexual health clinics
 - 8 in London
 - 5 in Birmingham, Brighton, Manchester, Sheffield, York
- Data collection: baseline self-completed demographic and behavioural paper CRFs
- Analysis: STATA v13

Baseline demographics (n=535)

- Median age 35
- Majority:
 - White ethnicity (78%)
 - UK born (59%)
 - University educated (61%)
 - Employed (72% full time; 10% part time)
 - Identify as gay/homosexual (95%)
 - Not in ongoing relationship (54%)
 - 30% living with partner

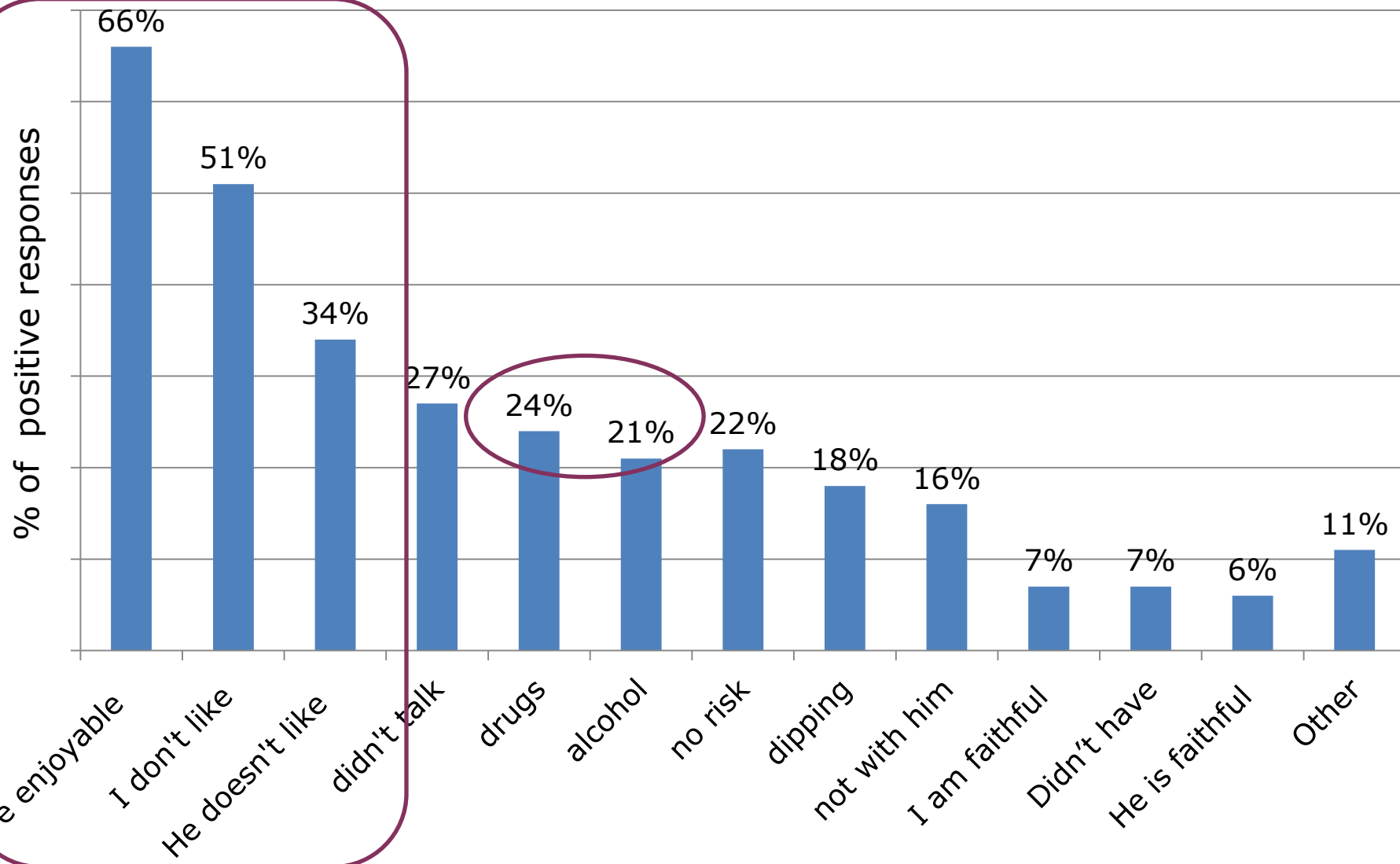
Baseline Behaviour

- High use of recreational drugs
 - 73% used recreational drugs in last 3 months
 - 43% used recreational drugs associated with chemsex
- Frequent attendance at sexual health clinics
 - Median 3 visits in last year for HIV testing
 - Median 3 visits in last year for STI testing
- High PEP use
 - 36% used in last year
 - 14% used more than once in last year
- High STIs
 - 64% self-reported STI in last year

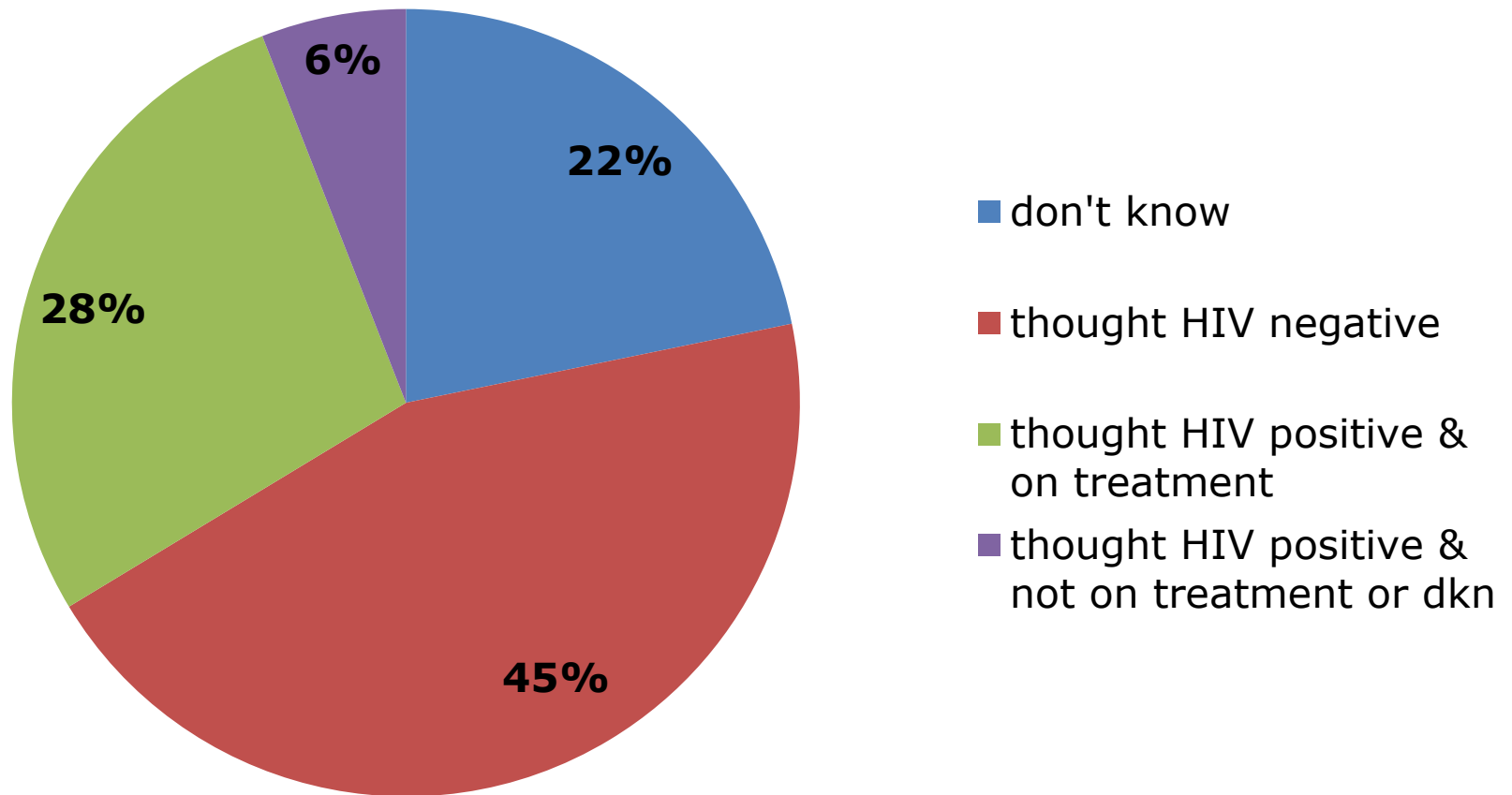
Baseline Sexual Behaviour

- Median on 10 anal sex partners in last 90 days
 - Median 2 partners condomless as receptive
 - Median 2 partners condomless as insertive
 - Median 7 new partners

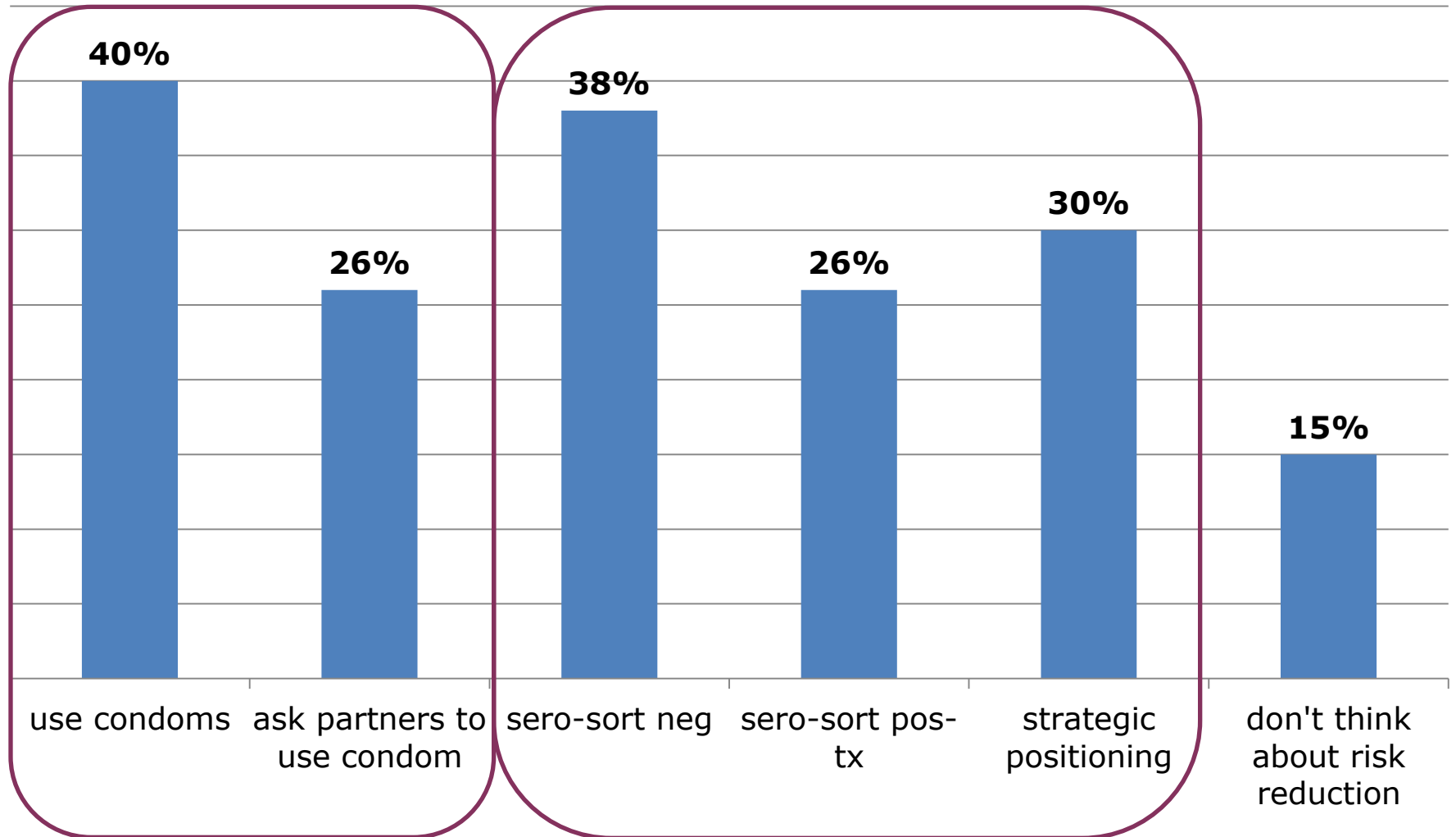
Reasons for not using a condom at last condomless anal sex



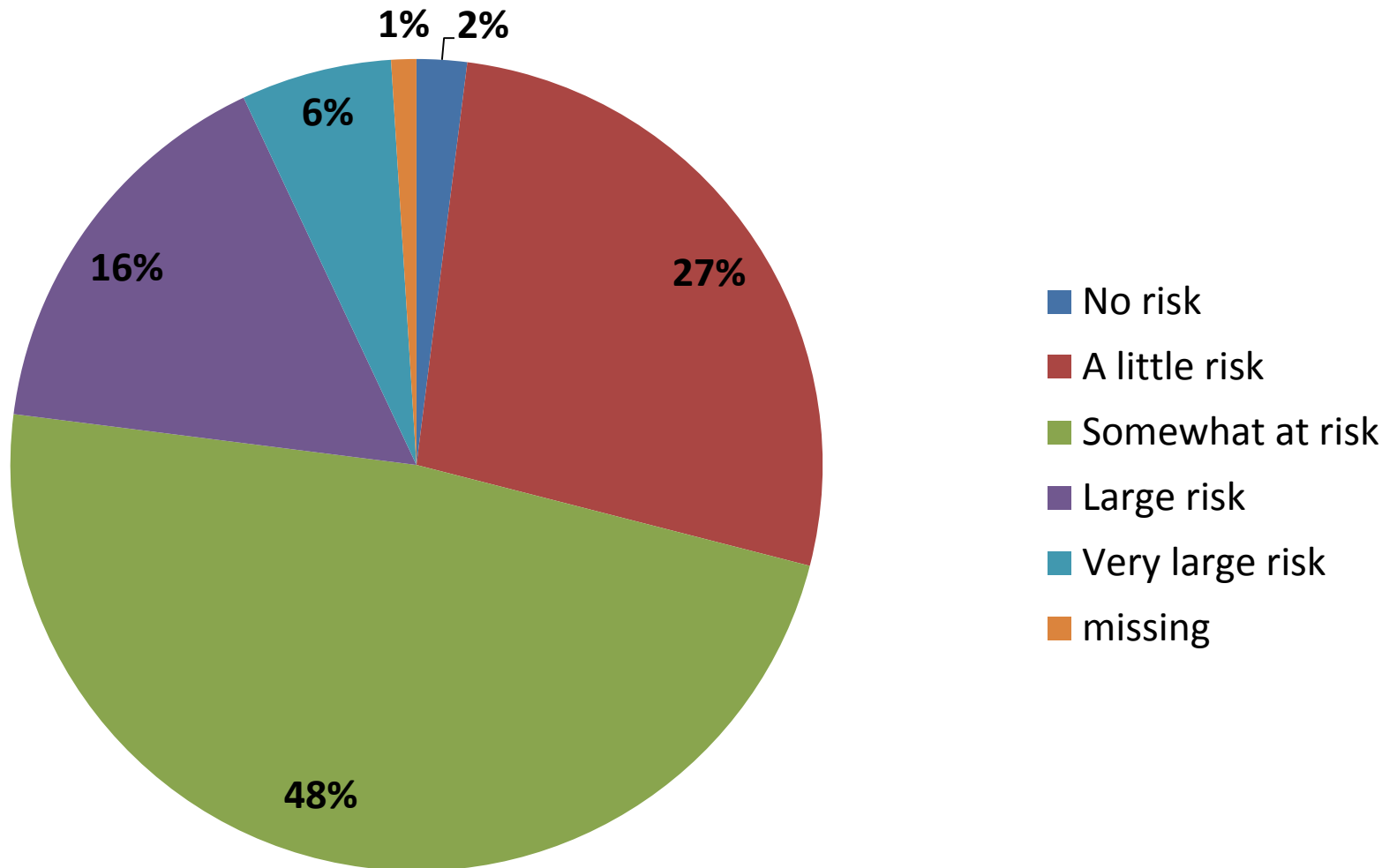
HIV status of last condomless anal sex partner



General HIV risk management strategies



General perception of HIV risk during condomless anal sex



Summary

- The PROUD cohort:
 - Median age similar to age at diagnosis
 - Highly educated, predominately employed
 - Engaged with SH clinics & using PEP for prevention
- In comparison to other UK data, participants report higher rates of:
 - Condomless anal sex partners ¹
 - STIs²
 - PEP use³
 - Drug use, especially drugs associated with chemsex⁴

¹Phillips et al. (2013) Increased HIV Incidence in MSM Despite High Levels of ART-Induced Viral Suppression. PLoS ONE 8(2); ²<http://www.hpa.org.uk/stiannualdatatables>; ³PHE. STI annual data tables. Table 5: All STI diagnoses & services by gender & sexual risk, 2009-2013; ⁴http://www.ihra.net/files/2012/09/04/Chapter_3.3_MSM_.pdf

Summary

- Large majority of participants perceived themselves to be at risk
 - Significantly higher perception of risk in those with a recent history of STIs
- Active management of risk at enrolment
 - Appeared to be polarised: condoms or sero-sorting
- PROUD attracted gay men at suitably high risk of HIV to benefit from PrEP.

Next Steps

- PROUD results scheduled for release Q1 2015
 - CROI/Lancet
- Community organisations revising statement
- BASHH-BHIVA plan to revise position statement
- Clinical reference PrEP sub-group
- PROUD pilot – ongoing follow up to April 2016
- HTA revised trial application

Acknowledgements (1)



Study participants

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Acknowledgements (2)



Trial Steering Committee

Independent members: Mike Adler (Co-Chair), Gus Cairns (Co-Chair), Dan Clutterbuck, Rob Cookson, Claire Foreman, Stephen Nicholson, Tariq Sadiq, Matthew Williams

Investigator members: Brian Gazzard, Noel Gill, Anne Johnson, Sheena McCormack, Andrew Phillips

Gilead

Matt Bosse, Rich Clarke, Jim Rooney, Murad Ruf

University of Liverpool

Saye Khoo

Independent Data Monitoring Committee

Anton Pozniak, Simon Collins, Fiona Lampe

Community Engagement Group

Community: Yusef Azad (NAT), Gus Cairns (NAM), Rob Cookson (LGF), Tom Doyle (Mesmac), Justin Harbottle (THT), Marion Wadibia (NAZ), Matthew Hodson (GMFA), Cary James (THT), Roger Pebody (NAM)

Clinics: Anthony Bains, Alan McOwan (Lead),

MRC CTU at UCL: Sheena McCormack, Mitzy Gafos, Annabelle South

PHE: Georgina Fletcher

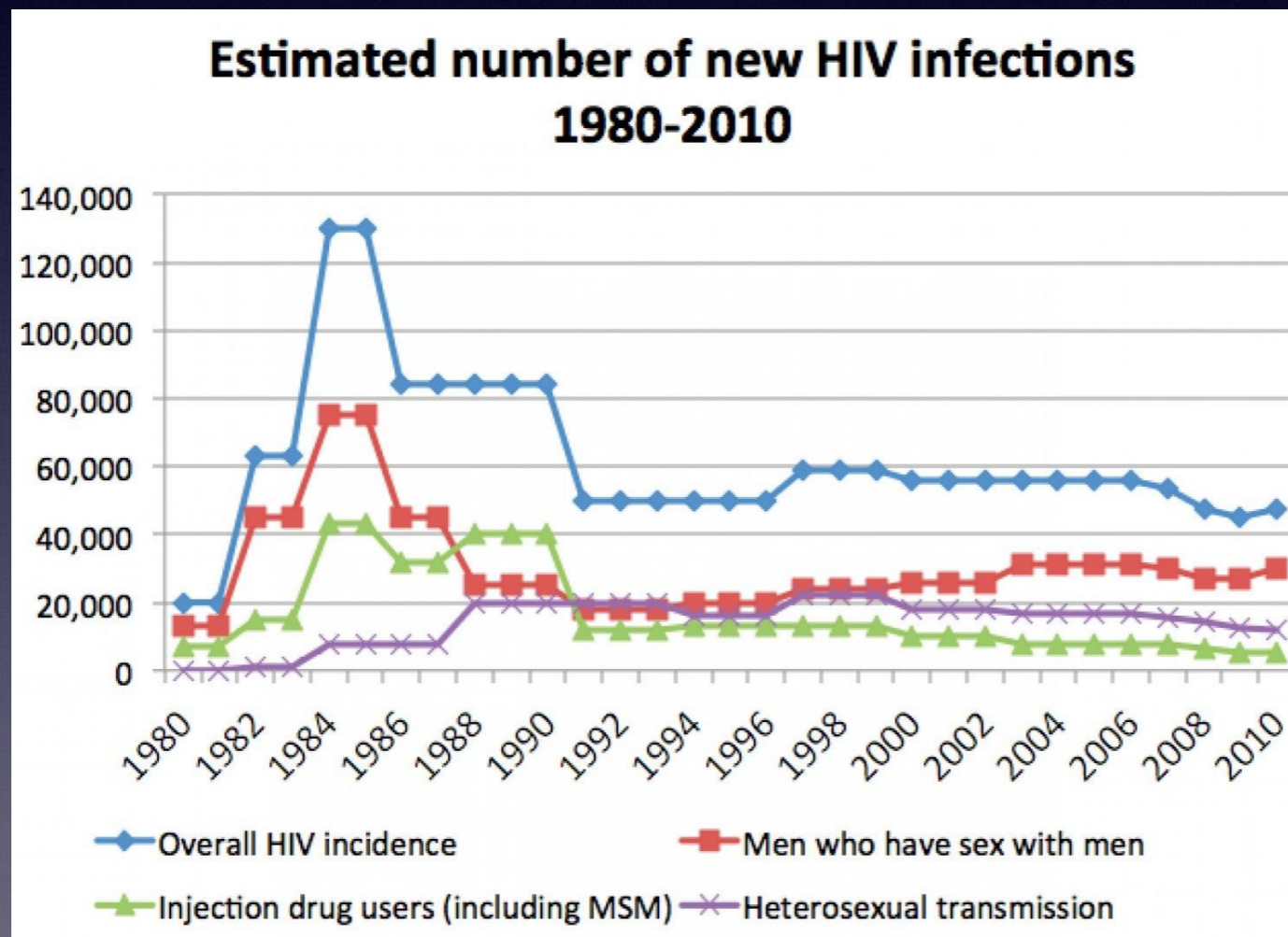
PrEParing For P.L.E.A.S.U.R.E.

by Damon L. Jacobs,
Licensed Marriage and Family Therapist

In the early days, “condoms only” was the only accepted approach to HIV education and prevention



Despite our best prevention efforts, new HIV diagnoses have remained stagnant for over a decade in the U.S.



- Following the FDA approval of Truvada for PrEP on July 16, 2012, came the stigma associated with use of this prevention regimen.



David Duran  [Become a fan](#)   
Freelance Journalist

Truvada Whores?

Posted: 11/12/2012 7:59 pm EST | Updated: 01/12/2013 5:12 am EST

On July 1, 2013, I started the first international group in social media using FaceBook. Named “PrEP Facts: Rethinking HIV Prevention and Sex, this was an opportunity for people anywhere in the world to receive:

Science

Research

Opinions

Facts

Tools for Discussing PrEP with Doctors

Adherence Support

Skills for Confronting Stigma

Friendship

Community

Occasionally a date!

People use PrEP to Experience P.L.E.A.S.U.R.E.

Peace of mind

Living without fear

Expectations of staying HIV negative

Agency

Satisfying Sex

Unity

Responsibility

Efficacy for bottoms